DETAILED ACTION

Election/Restrictions

1. Claims 3 and 6-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 24 September 2009.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. A review of the disclosure fails to find where applicant has provided a definition for the term "assay."

5. *Webster's New World College Dictionary*, accessed online 28 march 2010, defines "assay" thusly:

assay definition

ə-sā' (**as'ā, a sā'**; *for v.* **a sā', ə-**)

noun

1. an examination or testing
2. the analysis of an ore, alloy, drug, etc. to determine the nature, proportion, or purity of the ingredients
3. a substance to be thus tested or analyzed
4. the result or report of such an analysis
5. RARE an attempt

6. Accordingly and for purposes of examination, the term has been given its common meaning, which coincides with either of the first two meanings set from above.

7. Claims 1, 2, 4, and 5 are deemed to be incomplete as the claims are all drawn to a "nucleic acid assay," which is a method. The claims, however, do not recite any method steps. Rather, the claims provide a listing and characterization of the materials to be used in the assay.

8. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "assay" in claims 1, 2, 4, and 5 is used by the claim to mean "a set of reagents used as a system for identifying a substance" (applicant's response of 12 January 2010 at page 2), while the accepted meaning is "an examination or testing as well as the analysis of an ore, alloy, drug, etc. (*Webster's New World Dictionary)*" The term is indefinite because the specification does not clearly redefine the term.

Response to argument

9. At page 2, bridging to page 3, of the response of 12 January 2010, applicant asserts: "Although 'assay' may refer to a method for identifying a substance, the term is used in claim 1 to refer to a set of reagents used as a system for identifying a substance, in this case a specific sample nucleic acid sequence."

10. The above argument has been considered and has not been found persuasive. It is noted that applicant, at page 3, last paragraph, bridging to page 4, states:

> "Accordingly, it would be highly desirable to substantially reduce the amount of time and the number of steps required for preparing a sample and **performing the assay** without sacrificing desirable attributes such as sensitivity, low background "noise", and minimal "false positives". It would also be desirable to design an **assay** which can be carried out directly on cell lysates utilizing minimal nucleic acid material and significantly minimizing erroneous signal production typically associated with procedures that require polymerase chain reaction processing. It would be a significant advance in the art of detecting and identifying nucleic acid sequences to further provide a nucleic acid **assay** that significantly reduces the complexity and the labor needed to prepare the nucleic acid samples and conduct the **assay** which can be carried out using conventional laboratory reagents, equipment and techniques.

As readily seen above, applicant, at the time of filing, used the term "assay" in at least four occasions which all referred to a method, not an assortment of reagents to be used in a method.

11. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

14. The method of said claims requires the use of matrix and probe oligonucleotides. A review of the specification fails to find where applicant has provided an adequate written description of the essential starting materials and reaction conditions so as to reasonably suggest that applicant was in possession of the generic method at the time of filing. In particular, it is noted that the disclosure has not been found to set forth any SEQ ID NO. for any matrix/dendrimer or for any probe.

15. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

16. As set forth in *In re Alonso* 88 USPQ2d 1849 (Fed. Cir. 2008), at 1851:

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention …." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997); *see also LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 [76 USPQ2d 1724] (Fed. Cir. 2005); *Eiselstein v. Frank*, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 1995).

Alonso at 1852:

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when

coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo*, 323 F.3d at 964.

17. In applying the test as set forth in *Alonso*, it is noted that applicant is claiming a generic "nucleic acid assay for detecting the presence of a specific nucleic acid sequence in a sample suspected of containing the same" wherein the method requires use of a matrix as well as "at least one invader oligonucleotide for attaching to the first matrix," and "at least one probe oligonucleotide for attaching to the second site of the matrix, said probe oligonucleotide having a first probe nucleotide portion for binding to a second portion of the sample nucleic acid sequence and a second probe nucleotide portion which does not bind to the sample nucleic acid sequence."

18. While there is no *per se* rule requiring the disclosure of specific nucleotide sequences, applicant is still, nonetheless, required to provide a full, clear, and concise description of the reagents that are to be used in the claimed method, and that the disclosure needs to be of sufficient breadth so as to reasonably suggest that applicant was in possession of the full scope of the claimed invention.

19. In assessing whether applicant has provided 'a representative number of species in that genus ," it is noted that applicant has disclosed none. Turning to the second aspect of the written description test, it is noted that applicant has not provided the "its 'relevant identifying characteristics,' such as 'complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'

At page 5, last paragraph, bridging to page 6, assertions are made as to what one of skill in the art would have known or been capable of doing. It is noted that no supporting documentation has been provided.

20. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

21. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634